(hereinafter "Mandris") and US Patent No. 5,756,719 (hereinafter "Chaundry").

As per the arguments and amendments contained herein, reconsideration and allowance of all of the pending claims is respectfully requested. No new matter has been added by amendment, either to the specification or to the claims. All new paragraphs added to the specification are directly supported by the claims as originally filed.

REJECTIONS UNDER 35 USC 112, FIRST PARAGRAPH

The Examiner has rejected claims 51-64, 73-75, 79, and 80-106 under 35 USC 112, first paragraph.

Specifically, claims 51-64 were rejected for containing new matter, in that claim 51 was previously amended to include the phrase "with the proviso that no classification step is performed during the microencapsulation process." Additionally, amended claim 106 was rejected for containing new matter as containing the phrase "with the proviso that no grinding, sorting, or separation step is performed. As claims 51 and 106 are similar in their rejection, they will be discussed together below.

The Applicant respectfully disagrees with the assertion that the introduction of a proviso negating a classification step (claim 51) and/or a grinding, sorting, or separation step (claim 106) is new matter. Specifically, the specification as a whole teaches multiple compositional attributes that are consistent with a final product that is produced without the use of a classification and/or grinding, sorting, or separation step. The product, as produced according to the processes of the present invention, can be used directly to deliver a core material, such as a drug. The state of delivery upon completion of the present process provides evidence of this. Examples of such teachings include statements wherein the product is characterized as 1) quick and inexpensive to produce, 2) fine particles that exhibit excellent sustained-release properties, and 3) free flowing powder. See page 6, lines 11-13; page 6, lines 22-23; and page 7, line 11, respectively. Additionally, the specification also teaches that the fine particle sized exhibits excellent flow properties, and may be used as a food additive, incorporated into a powdered drink mix, or manufactured into solid dosage forms. See page 7, lines 20-22. Still further, the Examples make it clear that the

product is prepared and tested after a single preparative cycle. This fact provides a strong suggestion that there is no classification step, as classification typically leads to the reuse and/or recycling of material that has been separated out. Otherwise, a great deal of waste would be required. Nowhere is there a suggestion to classify or grind the powder in the present disclosure. As is known by those skilled in the art, flowability of powdered material can be desired for sustained-release compositions and methods of preparing the same. Such compositions have been formed, in the prior art, by classification and/or grinding steps. Flowability can be defined as the ability of a powder or particulate substance to flow evenly, by means of gravity and other forces. All of the Examples teach that after discharge, resulting granules are small, free-flowing, and exhibit sustained-release properties, all without the requirement of grinding, sorting, separating and/or classifying. In fact, the sustained release tests of the Examples demonstrate that the resultant product is acceptable, without the extra steps listed above. This also provides a basis for such a claim limitation. Therefore, reconsideration of the rejection of this phrase under 35 USC 112, second paragraph, is respectfully requested.

Claims 58-60, 73-75, 87-89, and 99-101 were rejected under 35 USC 112, first paragraph, as containing new matter. Specifically, the Examiner alleged that the ranges "of about 3-50% or 3-20% or 3-10%" are new matter, and that the originally filed claims support only from 5-30% by weight of oil. Though claim 19, as filed, does recite 5-30%, this is only a single embodiment. Upon inspection of originally filed claims 5-7, it is evident that "about 3-50% by weight," "about 3-20% by weight," and "about 3-10% by weight" are clearly supported by the originally filed application. As these ranges were in the originally filed specification, they have been amended into the detailed description, relying on originally filed claims 5-7 for support.

The Examiner has also rejected claims 62, 64, 77, 79, 91, 93, 103, and 105 under 35 USC 112, first paragraph, as containing new matter. Specifically, the Examiner has alleged that the ranges of sugar or oil (or mineral) is not supported by the specification. The specification has been amended to include these ranges, relying on originally filed claims 11, 15, 16, and 17 for support. Reconsideration of this rejection is respectfully requested.

Claims 80-93 have also been rejected under 35 USC 112, first paragraph, as containing new matter. Examples 2 and 3 both teach that work input or speed of rotation can be increased to 2000 RPM, and Example 2 teaches that the RPM can be adjusted down to 600 RPM. To adjust RPM down, all RPM revolutions between 2000 RPM and 600 RPM are passed through. Therefore, the Applicant asserts that each and every RPM value from 600 RPM to 2000 RPM is fully supported by the specification. Reconsideration is respectfully requested.

The Examiner has also rejected claim 94 under 35 USC 112, first paragraph, as containing new matter. The Examiner has alleged that the recitation of "any oil having the maximum iodine value of 5.0" is new matter as the support in the application is for "soy oil." Therefore, claim 94 has been amended to remove reference to the limitation relating to the "maximum iodine value of 5.0." Dependent claim 107 has been added that limits the claim to soy oil having a maximum iodine value of 5.0. Reconsideration of this rejection is respectfully requested.

REJECTIONS UNDER 35 USC 112, SECOND PARAGRAPH

The Examiner has rejected claims 51, 57, 68, 70, 72, 82, 84, 86, 96, and 98 under 35 USC 112, second paragraph.

With respect to claim 51, clarification of what is meant by "classification step" has been requested by the Examiner. Classification is a term that is known by those skilled in the art. It generally refers to a step where common physical characteristics are used to uniformly group a sample of powder or particulates. Such a step is not required with respect to the present invention, as described previously with respect to claims 51 and 106. Withdrawal of this rejection is requested.

Claims 57, 72, 86, and 98 have been amended as suggested by the Examiner. Specifically, the word "comprises" has been replaced with the word "is." Withdrawal of this rejection is respectfully requested.

With respect to claim 68, the phrase "mixer work input" is explained by example on page 7, lines 3-9, where "the oil or fat can be melted by the work input from the mixer itself . . . This results in the mixing, blending and melting of the oil with the other core materials all in the same process and within minutes." In other words, mixing work input generates heat that is used to melt the oil or fat. Based upon this clarification, reconsideration of this rejection is respectfully requested.

The Examiner has also suggested amending claims 70, 84, and 96 in order to provide proper Markush group formatting. These amendments have been made in accordance with the suggestion of the Examiner. Reconsideration is respectfully requested.

REJECTIONS UNDER 35 USC 103(a)

The Examiner has rejected claims 51-106 under 35 USC 103(a) as being unpatentable over the combination of Mandris and Chaundry. It appears that the Examiner has examined the claims without considering the "proviso" language found in claim 51 and claim 106. As the 35 USC 112, first paragraph, rejections related to this language are believed to have been overcome, further consideration is requested. In addition to this, the independent claims, where applicable, have been amended to clarify that no added water is used at any stage to prepare the compositions of the present invention. Chaundry and Mandris only describe compositions and methods where the presence oil/water emulsions are part of the preparative method. Therefore, the rejections related to these references are thought to be rendered moot by the Applicant's amendment herein. Support for this amendment can be found in the Examples where complete compositions are fabricated and tested for a release profile without the addition of water. Reconsideration is respectfully requested.

Applicants submit that each and every amendment herein, and throughout the prosecution of the present application is fully supported by the specification as originally filed, and that no new matter has been added. With respect to the amendments to the specification, some amendments were made to what are considered obvious typographical errors. Additionally, the new paragraphs are literally supported by the originally filed claims, namely claims 3-7, 11-17, 19-27, and 29.

In view of the foregoing, Applicants believe that claims 51-107 present allowable subject matter and allowance is respectfully requested. If any impediment to the allowance of these claims remains after consideration of the above remarks, and such impediment could be alleviated during a telephone interview, the Examiner is invited to telephone the undersigned attorney at (801) 566-6633, so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 28th day of October, 2002.

Respectfully submitted,

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AMENDMENTS

(marked-up version of specification)

In the specification, please replace the paragraph starting on page 3, line 6, with the following:

> Fluid bed granulation or coating is one of the most common techniques used at the present time for small particle sustained-release. Fluidized bed equipment is available as "top spray", "bottom spray", and "tangential-spray". The core drug is first preheated in the vessel to about 30°C with hot air, placing the particles in suspension. The floating particles are then sprayed with an aqueous suspension to provide a coating, while drying at the same time. Inlet temperature, spray rate, and air throughput must be adjusted to provide optimum end product. Furthermore, the finished particles must be subjected to a post-drying period at around 40°C, where any residual moisture can be driven off. In some case, this last drying period may be up to 24 hours.

In the specification, please replace the paragraph starting on page 3, line 15, with the following:

> Many of the polymers that are used to provide sustained-release properties to powders in the fluid bed process require solvents such as acetone, isopropyl alcohol, chlorinated solvents, alkanes, methyl ethyl ketone, cyclohexane, toluene, carbon tetrachloride, chloroform, and the like. Evaporation of the solvents becomes an environmental concern, and in many states it is illegal to release these emissions into the atmosphere. Aqueous or water based polymers are limited mainly to ethyl cellulose and methacrylic acid esters such as poly methacrylate dispersions. In addition, 10-20% of a suitable plasticizer such as triethyl citrate must be added to the polymer. For example, U.S. Patent No. ~~patent #~~ 5603957 uses a solvent-based polymer system to deliver

aspirin over a 24-hour period. Prefered solvents are acetone/alkanol mixtures, or cyclohexane, toluene, or carbon tetrachloride. Castor oil, a low melting point oil, is also included in the polymer solvent mix.

In the specification, please replace the paragraph starting on page 6, line 19, with the following:

In accordance with the invention, there is provided a microsphere that is produced by mixing the therapeutic agent with a hot vegetable oil with a melting point at least above 110°C, and preferably about 160 degrees F, in a vertical or horizontal high intensity shear ~~schear~~ mixer until the particles or the core substance are thoroughly mixed with the oil, and then cooling the hot melt to produce fine particles that exhibit excellent sustained-release properties. Surprisingly, the entire process can be completed in about 10 minutes or less, utilizing the work input of the mixer to melt the oil and intimately mix it with the core agent. The ideal high temperature melting point oil for this process is a hydrogenated soy oil with a maximum iodine value of 5.0 and a melting point of 150-160°C. Such an oil with these specifications is Dritex S® in flake form or Sterotex HM® which is a spray chilled, powder. Both are available from AC Humko, Memphis TN. The melting point profile is more uniform if the spray chilled powder is used.

In the specification, please replace the paragraph starting on page 7, line 30, with the following:

Oils such as low melting point vegetable oil, castor oil, baby oil, margarine, cocoa butter, paraffin ~~pariffin~~, and the like have also been used in the pharmaceutical industry for a variety of purposes, but not as sustained-release agents. For example, soft oils are often used for suppositories. These oils cannot be used to provide solid particles at room temperature. Various resins and shellac have also been used, but usually not for sustained-release. Carnauba wax is widely used in pharmaceutical dosage forms.

In the specification, please replace the paragraph starting on page 8, line 27, with the following:

The core material may be selected from any suitable drug, therapeutic or prophylactic agent, nutritional agent, biological substance, fungicide, food or

botanical substance, fertilizer, or animal feed, which can be incorporated in the hot melt without losing substantial activity for the chosen therapy. A broad range of materials ~~are~~ is therefore useful. Representative non-limiting classes of drugs or nutritional agents useful include those falling into the following therapeutic categories:

In the specification, please replace the paragraph starting on page 9, line 22, with the following:

Non-limiting examples of specific therapeutic agents which may be useful in the present invention can be chosen from the list which follows. Mixtures of these agents and their salts used for appropriate therapies are also contemplated: acetaminophen; acetic acid-, acetylsalicylic acid and its buffered form; albuterol and its sulfate; alcohol; alkaline phosphatase; allantoin; aloe; aluminum acetate, carbonate, chlorohydrate, hydroxide-alprozolam; amino acids; aminobenzoic acid; amoxicillin; ampicillin; ansacrine; amsalog; anethole; ascorbic acid; aspartame; aspirin; atenolol; bacitracin; balsam peru; BCNU (carmustine) beclomethasone dipropionate; benzocaine; benzoic acid; benzophenones;; benzoyl peroxide; bethanechol; biotin; bisacodyl; bomyl acetate; bromopheniramine maleate; buspirone; caffeine; calamine; calcium;; calcium carbonate;; casinate and hydroxide; camphor; captopril; cascara sagrada; castor oil; cefaclor; cefadroxil; cephalexin; cetylalcohol; cetylpyridinium chloride; chelated minerals; chloramphenicol; chlorcyclizine hydrochloride; chlorhexidine gluconate; chloroxylenol; chloropentostatin; chlorpheniramine maleate; cholestyramine resin; choline bitartrate; chondrogenic stimulating protein; cimetidine hydrochloride; cinnamedrine hydrochloride; citalopram; citric acid; cocoa butter; cod liver oil; codeine and codeine phosphate; clonidine and its hydrochloride salt, clorfibrate; cortisone acetate; ciprofloxacin HCl ~~HC-I~~; cyanocobalamin; cyclizine hydrochloride; danthron; dexbrompheniranime maleate; dextromethorphan hydrobromide; diazapam; dibucaine; diclofenac sodium; digoxin; diltiazem; dimethicone; dioxybenzone; diphenhydramine citrate; diphenhydramine hydrochloride; docusate calicum, potassium and sodium; doxycycline hyclate; doxylamine succinate; efaroxan; enalpril; enoxacin; erythromycin; estropipate; ethinyl estradiol; ephedrine; epinephrine

bitartrate; erythropoictin; eucalyptol; ferrous fiamarate, gluconate and sulfate; folic acid; fosphenytoin; 5-fluorouracil (5-FU) fluoxetine HCl ~~HCl~~; furosemide; gabapentan; gentamicin.-gemfibrozil; glipizide; glycerin; glyceryl stearate; griseofulvin; growth hormone; guaifenesin; hexylresorcinol; hydrochlorothiaxide; hydrocodone bitartrate; hydrocortisone and its acetate; 8-hydroxyquinoline sulfate; ibuprofen; indomethacin; inositol; insulin; iodine; ipecac-, iron; isoxican; ketamine; kaolin; lactic acid; lanolin; lecithin; leuprolide acetate; lidocaine and its hydrochloride salt; lifinopril; liotrix; lovastatin; luteinizing hormone; LHRH (luteinizing hormone releasing hormone),- magnesium carbonate, hydroxide, salicylate; trisilocate; mefenamic acid; meclofenanic acid; meclofenamate sodium; medroxyprogesterone acetate; methenamine mandelate; menthol; meperidine hydrochloride; metaproterenol sulfate; methyl nicotinate; methyl salicylate; methylcellulose; methsuximide; metronidazole and its hydrochloride; metoprolol tartrate; miconazole nitrate; mineral oil; minoxidil; morphine; naproxen and its sodium salt; nifedipine; neomycin sulfate; niacin; – niacinamide; nicotine; nicotinamide; nitroglycerin; nonoxynol-9; norethindone and its acetate; nystatin; octoxynol; octoxynol 9; octyl dimethyl PABA, octyl. methoxycinnamate; omega-3 polyunsaturated fatty acids; omeprazole; oxolinic acid; oxybenzone; oxtriphylfine; para-aminobenzoic acid (PABA); padimate 0; paramethadoine; pentastatin; peppermint oil; pentaerythriol tetranitrate; pentobarbital sodium; pheniramine maleate; phenobarbital; phenol; phenolphthalein; phenylephrine hydrochloride; phenylpropanolamine and its hydrochloride salt; phenytoin; phenelzine sulfate; pirmenol; piroxicam; polymycin B sulfate; potassium chloride and nitrate; prazepam; procainamide hydrochloride; procaterol; propoxyphene and its HCl ~~HC l~~ salt; propoxyphene napsylate; pramiracetin; pramoxine and its hydrochloride salt; propronolol HCl ~~HC l~~; pseudoephedrine hydrochloride and sulfate; pyridoxine; quinapril; quinidine gluconate and sulfate; quinestrol; ralitoline; ranitidine; resorcinol; riboflavin; salicylic acid; sesame oil; shark liver oil; simethicone; sodium bicarbonate; citrate and fluoride; sodium monofluorophosphate; sucralfate; sulfanethoxazole; sulfasalazine; sulfur; tacrine and its HCl ~~FIC l~~ salt; theophylline; terfenidine; thioperidone; trimethrexate; triazolam; timolol

maleate; tretinoin; tetracycline hydrochloride; tolmetin; tolnaftate; triclosan; triprolidine hydrochloride; undecylenic acid; vancomycin; verapamil HCl ~~HC~~ ~~I~~; vidaribine phosphate; vitamins A, B., C., D, B1 ~~B-1~~, B2, B 6, B12, E, K; witch hazel; xylometazoline hydrochloride; zinc; zinc sulfate; zinc undecylenate.

In the specification, please replace the paragraph starting on page 11, line 16, with the following:

The inventive compositions have great versatility in their application. The compositions can be used for wound management such as by direct application to burns ~~buns~~, abrasions, skin diseases or infections and the like. Other uses such as packing agents for nasal wounds or other open wounds are also contemplated.

In the specification, please replace the paragraph starting on page 12, line 5, with the following:

Useful additives include, for example, gelatin, vegetable proteins such as sunflower protein, soybean proteins, cotton seed proteins, peanut proteins, rape seed proteins, blood proteins, egg proteins, acrylated proteins; water-soluble polysaccharides such as alginates, carrageenans, guar gum, agar-agar, gum arabic, and related gums (gum ghatti, gum karaya, gum tragacanth), pectin, water-soluble derivatives of cellulose: alkylcelluloses, hydroxyalkyl celluloses and hydroxyalkylalkylcelluloses, such as methylcellulose, hydroxymethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxyethylmethylcellulose, hydroxpropylmethylcelluose ~~hydroxpropylmethylceflulos~~, hydroxbutylmethylcellulose ~~hydroxbutylmethylceflulose~~, cellulose esters and hydroxyalkylcellulose ~~hydroxyalkylceRuloso~~ esters such as: cellulose acetate phthalate (CAP), carboxyalky I celluloses, carboxyalkylalkylcelluloses, carboxyalkylcellulose esters such as carboxymethyl cellulose and their alkali metal salts; water-soluble synthetic polymers such as polyacrylic acids and polyacrylic acid esters, polymethacrylic acids and polymethacrylic acid esters, polyvinylacetates, polyvinylalcohols, polyvinylacetatephthalates (PVAP), polyvinylpyrrolidone (PVP), PVP/vinyl acetate copolymer, and polycrotonic acids; also suitable are phthalated gelatin, gelatin succinate, crosslinked

gelatin, shellac, water-soluable chemical derivatives of starch, cationically modified acrylates and methacrylates possessing, for example, a tertiary or quaternary amino group, such as the diethylaminoethyl ~~diethylan-finoethyl~~ group, which may be quaternized if desired; and other similar polymers.

In the specification, please replace the paragraph starting on page 12, line 22, with the following:

Processing aids such as sucrose, polydextrose, dextrose, maltodextrin, lactose, maltose, and the like may also be used. In some cases where accelerated release is desired, a sugar may be incorporated into the hot melt. Since the oil coating is hydrophobic, incorporating a hydrophilic sugar in the hot melt helps counteract the tendency of the particles to float. The sugar also helps to increase the rate of release of the core material by providing solubility to the matrix. Sugar may be present in the melt from 1-30% by weight of the finished particles. In some embodiments of the present invention, the sugar is present in the melt from 5-20% by weight of the finished particles. For example, the sugar may be present in the melt at about 10% by weight of the finished particles. Other substances such as calcium carbonate or other minerals can be added to provide weight to the particles and affect ~~effect~~ the release profile.

In the specification, please replace the paragraph starting on page 13, line 6, with the following:

Example 1:

Niacin (nicotinic acid) is added to a plow mixer, which was capable of operating at high temperatures because it was jacketed with a second layer to allow hot water to flow around the vessel. The unit was fitted with a tower-mounted, hydraulic atomizing nozzle with heated tanks and heated/insulated lines to enable hot oil to be applied at high temperatures. A high speed chopper operating at 10 hp was fitted at the discharge point. Hydrogenated soy oil flakes(Dritex S®, AC Humko, Memphis, TN) with a melting point of about 80°C or 140-160°C ~~80°C or 140-160F~~ was sprayed on the powder as it was mixing in vessel. Efficient coating or microencapsulation of the powder was achieved in about 30 minutes when a temperature of about 155°F was reached and the hot oil thoroughly mixed with the powder. Cooling was

achieved by discharging the batch into a cooler mounted directly below the mixer. The resulting granules were small, free flowing, and exhibited sustained-release properties when a dissolution test was conducted. The weight percent of the niacin in the finished product was 90%, and the hydrogenated soy oil was 10%.

Please insert the following paragraph on page 8, line 20:

Animal or vegetable oils may be used in the present invention. Such oils may have a melting point between 120 degrees F and 200 degrees F. In one embodiment, the oils may have a melting point of 110-200 degrees F. In another embodiment, the oils may have a melting point of 120-180 degrees F. For example, hydrogenated soy oil having a melting point of about 160 degrees F may be used. Hydrogenated soy oil may also have a melting point in the range of about 145-160 degrees F. Another example of an oil for use in the present invention is hydrogenated vegetable oil with a melting point above 110 degrees F.

Please insert the following paragraph on page 8, line 25:

The oils used in the present invention may be provided in an amount such that the finished sustained-release particle contains oil in about 3% to 50% by weight of the finished particle. In another aspect of the present invention, the particle may contain oil in about 5% to 30% by weight of the finished particle. The particle may also contain oil in about 3% to 20% by weight of the finished particle. In another aspect of the present invention, the particle may contain oil in about 3% to 10% by weight of the finished particle. Thus, the particle may contain oil in about 5% by weight of the finished particle.

Please insert the following paragraph on page 12, line 28:

A mineral may also be present in the melt from 1-20% by weight of the finished particles. In some embodiments of the present invention, the mineral may be present in the melt from 5-10% by weight of the finished particle. For example, calcium carbonate may be provided in the melt at about 5% by weight of the finished particle.

(marked-up version of claims)

Please amend claim 51 as follows:

51. (Amended) A microencapsulation process comprising:

a) adding a core material and an oil having a melting point above about 110 Deg. F., without added water, into a mixer;

b) mixing the core material and the oil until microencapsulated particles are formed that comprise the core material and the oil; and

c) discharging the microencapsulated particles;

with the proviso that no classification step is performed during the microencapsulation process.

Please amend claim 57 as follows:

57. (Amended) The microencapsulation process of claim 51, wherein the oil having a melting point above about 110 Deg. F is ~~comprises~~ a hydrogenated soy oil with a melting point of about 160 degrees F.

Please amend claim 65 as follows:

65. (Amended) A microencapsulation process compromising:

a) adding a core material, and an oil having a melting point above about 100 Deg. F., without added water, into a mixer;

b) simultaneously fluidizing and mixing the core material and the oil until microencapsulated particles are formed that comprise the core material and the oil; and

c) discharging the microencapsulated particles.

Please amend claim 70 as follows:

70. (Amended) The microencapsulation process of claim 65 wherein the core material is selected from the group consisting of ~~comprises~~ ace-inhibitors; anti-anginal drugs; anti-arrhythmias; anti-asthmatics; anti-cholesterolemics; anti-convulsants; anti-depressants; anti-diarrhea preparations; anti-histamines; anti-hypertensive drugs; anti-infectives; anti-inflammatory agents; anti-lipid agents; anti-manics; anti-nauseants; anti-stroke agents; anti-thyroid preparations; anti-tumor drugs; anti-tussives; anti-uricemic drugs; anti-viral agents; acne drugs; alkaloids; amino acid preparations; anabolic drugs; analgesics; anesthetics; angiogenesis inhibitors; antacids; antiarthritics; antibiotics; anticoagulants; antiemetics; antiobesity drugs; antiparasitics; antipsychotics; antipyretics; antispasmodics; antithrombotic drugs; anxiolytic agents; appetite stimulants; appetite suppressants; beta blocking

agents; bronchodilators; cardiovascular agents; cerebral dilators; chelating agents; cholecystokinin antagonists; chemotherapeutic agents; cognition activators; contraceptives; coronary dilators; cough suppressants; decongestants; deodorants; dermatological agents; diabetes agents; diuretics; emollients; enzymes; erythropoietic drugs; expectorants; fertility agents; fungicides; gastro-intestinal agents; growth regulators; hormone replacement agents; hyperglycemic agents; hypnotics; hypoglycemic agents; laxatives; migrain treatments; mineral supplements; mucolytics; narcotics; neuroleptics; neuromuscular drugs; NSAIDS; nutritional additives; peripheral vaso-dilators; polypeptides; prostaglandins; psychotropics; renin inhibitors; respiratory stimulants; steroids; stimulants; sympatholytics; thyroid preparations; tranquilizers; uterine relaxants; vaginal preparations; vaso-constrictors; vaso-dilators; vertigo agents; vitamins; wound healing agents; botanical substances; fungicides~~,~~; fertilizers~~,~~; niacin~~,~~; L-arginine~~,~~; creatine monohydrate~~,~~; L-carnitine~~,~~; aspirin~~,~~; loratidine~~,~~; lovastatin~~,~~; vitamin C~~,~~; garlic powder~~,~~; polygonum cuspidatum root extract~~,~~; astaxanthin~~,~~; tocotrienol and ~~or~~ co-enzyme Q-10.

Please amend claim 72 as follows:

72. (Amended) The microencapsulation process of claim 65, wherein the oil having a melting point above about 110 Deg. F is ~~comprises~~ a hydrogenated soy oil with a melting point of about 160 degrees F.

Please amend claim 80 as follows:

80. (Amended) A microencapsulation process comprising:

a) adding a core material, and an oil having a melting point above about 110 Deg. F., without added water, into a mixer;

b) mixing the core material and the oil, at a mixer work input ranging from 600 RPM to 2000 RPM, until microencapsulated particles are formed that comprise the core material and the oil; and

c) discharging the microencapsulated particles.

Please amend claim 84 as follows:

84. (Amended) The microencapsulation process of claim 80 wherein the core material is selected from the group consisting of~~comprises~~ ace-inhibitors; anti-anginal drugs; anti-arrhythmias; anti-asthmatics; anti-cholesterolemics; anti-convulsants; anti-depressants; anti-diarrhea preparations; anti-histamines; anti-hypertensive drugs; anti-infectives; anti-inflammatory agents; anti-lipid agents; anti-manics; anti-nauseants;

anti-stroke agents; anti-thyroid preparations; anti-tumor drugs; anti-tussives; anti-uricemic drugs; anti-viral agents; acne drugs; alkaloids; amino acid preparations; anabolic drugs; analgesics; anesthetics; angiogenesis inhibitors; antacids; antiarthritics; antibiotics; anticoagulants; antiemetics; antiobesity drugs; antiparasitics; antipsychotics; antipyretics; antispasmodics; antithrombotic drugs; anxiolytic agents; appetite stimulants; appetite suppressants; beta blocking agents; bronchodilators; cardiovascular agents; cerebral dilators; chelating agents; cholecystokinin antagonists; chemotherapeutic agents; cognition activators; contraceptives; coronary dilators; cough suppressants; decongestants; deodorants; dermatological agents; diabetes agents; diuretics; emollients; enzymes; erythropoietic drugs; expectorants; fertility agents; fungicides; gastro-intestinal agents; growth regulators; hormone replacement agents; hyperglycemic agents; hypnotics; hypoglycemic agents; laxatives; migrain treatments; mineral supplements; mucolytics; narcotics; neuroleptics; neuromuscular drugs; NSAIDS; nutritional additives; peripheral vaso-dilators; polypeptides; prostaglandins; psychotropics; renin inhibitors; respiratory stimulants; steroids; stimulants; sympatholytics; thyroid preparations; tranquilizers; uterine relaxants; vaginal preparations; vaso-constrictors; vaso-dilators; vertigo agents; vitamins; wound healing agents; botanical substances; fungicides~~,~~; fertilizers~~,~~; niacin~~,~~; L-arginine~~,~~; creatine monohydrate~~,~~; L-carnitine~~,~~; aspirin~~,~~; loratidine~~,~~; lovastatin~~,~~; vitamin $C_{,}$; garlic powder~~,~~; polygonum cuspidatum root extract~~,~~; astaxanthin~~,~~; tocotrienol and ~~or~~ co-enzyme Q-10.

Please amend claim 86 as follows:

86. (Amended) The microencapsulation process of claim 80, wherein the oil having a melting point above about 110 Deg. F is ~~comprises~~ a hydrogenated soy oil with a melting point of about 160 degrees F.

Please amend claim 94 as follows:

94. (Amended) A pharmaceutical composition comprising a microencapsulated core material, wherein the microencapsulated core material is microencapsulated by a formulation that ~~comprises~~ consists essentially of an animal or vegetable oil with a melting point above about 110 Deg. F. ~~and a maximum iodine value of 5.0.~~

Please amend claim 96 as follows:

96. (Amended) The pharmaceutical composition of claim 94, wherein the core material is selected from the group consisting of ~~comprises~~ ace-inhibitors; anti-anginal drugs; anti-arrhythmias; anti-asthmatics; anti-cholesterolemics; anti-convulsants; anti-depressants; anti-diarrhea preparations; anti-histamines; anti-hypertensive drugs; anti-infectives; anti-inflammatory agents; anti-lipid agents; anti-manics; anti-nauseants; anti-stroke agents; anti-thyroid preparations; anti-tumor drugs; anti-tussives; anti-uricemic drugs; anti-viral agents; acne drugs; alkaloids; amino acid preparations; anabolic drugs; analgesics; anesthetics; angiogenesis inhibitors; antacids; antiarthritics; antibiotics; anticoagulants; antiemetics; antiobesity drugs; antiparasitics; antipsychotics; antipyretics; antispasmodics; antithrombotic drugs; anxiolytic agents; appetite stimulants; appetite suppressants; beta blocking agents; bronchodilators; cardiovascular agents; cerebral dilators; chelating agents; cholecystokinin antagonists; chemotherapeutic agents; cognition activators; contraceptives; coronary dilators; cough suppressants; decongestants; deodorants; dermatological agents; diabetes agents; diuretics; emollients; enzymes; erythropoietic drugs; expectorants; fertility agents; fungicides; gastro-intestinal agents; growth regulators; hormone replacement agents; hyperglycemic agents; hypnotics; hypoglycemic agents; laxatives; migrain treatments; mineral supplements; mucolytics; narcotics; neuroleptics; neuromuscular drugs; NSAIDS; nutritional additives; peripheral vaso-dilators; polypeptides; prostaglandins; psychotropics; renin inhibitors; respiratory stimulants; steroids; stimulants; sympatholytics; thyroid preparations; tranquilizers; uterine relaxants; vaginal preparations; vaso-constrictors; vaso-dilators; vertigo agents; vitamins; wound healing agents; botanical substances; fungicides~~,~~; fertilizers~~,~~; niacin~~,~~; L-arginine~~,~~; creatine monohydrate~~,~~; L-carnitine~~,~~; aspirin~~,~~; loratidine~~,~~; lovastatin~~,~~; vitamin C~~,~~; garlic powder~~,~~; polygonum cuspidatum root extract~~,~~; astaxanthin~~,~~; tocotrienol and ~~or~~ co-enzyme Q-10.

Please amend claim 98 as follows:

98. (Amended) The pharmaceutical composition of claim 94, wherein the oil having a melting point above about 110 Deg. F is ~~comprises~~ a hydrogenated soy oil with a melting point of about 160 degrees F.

Please amend claim 106 as follows:

106. (Amended) A microencapsulation process comprising:

a) adding a core material and a non-aqueous medium comprising an oil having a melting point above about 110 Deg. F., without added water, into a mixer;

b) mixing the core material and the oil at substantially ambient pressure until microencapsulated particles are formed that comprise the core material and oil;

c) discharging the microencapsulated particles;

with the proviso that no grinding, sorting or separation step is performed.

Please add new claim 107 as follows:

107. (New) The pharmaceutical composition of claim 94, wherein the animal or vegetable oil is soy oil having a maximum iodine value of 5.0.